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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,190	06/02/2005	Paolo Corvi Mora	27419-230	1281

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NIXON PEABODY LLP
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EXAMINER

KOSAR, AARON J

ART UNIT	PAPER NUMBER
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1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/537,190	Applicant(s) CORVI MORA ET AL.	
	Examiner Aaron J. Kosar	Art Unit 1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02 June 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed June 2, 2005, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

2. The specification is objected to because of the following informalities: The term *aminoacid* represents a typographical error of *amino acid* (page 2, line 23). Appropriate correction is required.

Claim Objections

3. Claims 1,2,4, and 11 are objected to because of the following informalities: The term *aminoacid* represents a typographical error of *amino acid*. Appropriate correction is required.
4. Claim 11 is objected to because of the following informalities: The term *cyclodestrins* represents a typographical error of *cyclodextrins*. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1-11,15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims read upon a composition comprising an active substance, propolis, an amino acid, and a sweetening agent, glycyrrhizate. Claims 1 and 11 as written do not clearly point out whether the term *active substance* is intended to be limited by propolis or whether propolis is an example of an active substance. Each is a reasonable interpretation of the claim, but each is somewhat different in scope, so the metes and bounds of the claim are not clear. This affects all of the dependent claims. In a similar rejection in these claims, it is not clear if glycyrrhizate is intended to limit the term *sweetening agent* or if it merely provides an example.

Furthermore, in Claims 1-11, 15-21 the term *compositions* and *powders* in plurality may reasonably read upon multiple inventions within a single claim rather than any particular *composition* or powder. The claims as written differ in scope from a single composition, so the metes and bounds of the claim are not clear.

6. The term "finely divided" in Claims 1 and 11 is a relative term, which renders the claim indefinite. The term "finely divided" is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This affects all the dependent claims.

7. The term *comprising* in Claims 1 and 11 is open language and conflicts with the identity of a quaternary composition. It is unclear if the claimed composition consists of four elements or if the composition to have utility must have greater than four components. This affects all the dependent claims.

8. Claims 15 and 16 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the phrase "with or without excipients and diluents" is drawn to both excipients and diluents inseparably or if the presence or absence of excipients is independent of the presence or absence of diluents. Each is a reasonable interpretation of the claim, but each is somewhat different in scope, so the metes and bounds of the claim are not clear.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 15-18, 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claims 15-17 contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention. The claims read upon the quaternary composition of Claim 1 for respective use in dietary supplements, parapharmaceuticals, and dermocosmetics and also read upon product forms "with or without excipients and diluents suitable for the same". The examiner is interpreting this to indicate that excipients and diluents further comprise the quaternary composition of claim one; however, as discussed above, a quaternary composition cannot consist of more than four components.

Additionally, the specification only discloses a limited number of examples, but does not clearly define excipients and diluents necessary to make and/or use the invention as claimed. This also affects the dependent claims 18, 20-21.

Allowable Subject Matter

11. The following is an examiner's statement of reasons for allowable subject matter:

The Applicants invention as claimed requires the elements:

- a. Propolis
- b. a hydrophilic carrier
- c. an amino acid
- d. glycyrrhizate
- e. powder
- f. quaternary composition

As claimed, this combination has not been anticipated by the prior art. Examination of the prior art reveals that Aga, *et al* teaches a composition combining propolis, a hydrophilic carrier (cyclodextrin), and a sweetening agent (maltose) (column 12, lines 18-35, Example B-8). Aga also teaches a water-soluble, dry, powdery composition comprising: propolis, a hydrophilic carrier (sodium citrate), an amino acid (glycine), and a sweetening agent (trehalose) (column 14

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lines 27-4, Example B-15). While both trehalose and glycyrrhizic acid impart sweetness, they are not obvious variants, the former being a simple disaccharide and the latter a triterpenoid glycosidic saponin. A search of the prior art yielded no motivation for one of ordinary skill in the art to substitute glycyrrhizic acid for trehalose.

Additionally, the prior art according to Bettel, *et al* teaches the combination of an aqueous multi-component emulsion comprising propolis, a hydrophilic carrier (propylene glycol), and amino acid (glycine) (Example 12). Bettel also teaches a composition of propolis, propylene glycol, amino acids (arginine, proline, L-glutamine), and glycyrrhizate (Example 13); however, the prior art teaches 49- and 48-component compositions, respectively, not a quaternary mixture. Bettel also uses glycine in emulsion formulations excluding glycyrrhizic acid and glycyrrhizic acid in compositions excluding glycine. One of ordinary skill in the art would, therefore, not be motivated by Bettel to select the four components where glycyrrhizic acid and glycine are used together in powdery formulations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 272-0235. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0235. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron J. Kosar
Patent Examiner



MARY E. MOSHER, PH.D.
PRIMARY EXAMINER